

Notice of Allowability	Application No.	Applicant(s)	
	09/693,555	KORNMAN ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10-23-03.
2. ☒ The allowed claim(s) is/are 1,3,4,6,7 and 85.
3. ☒ The drawings filed on 20 October 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____ | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

EXAMINER'S AMENDMENT

EXAMINER'S COMMENT/REASONS FOR ALLOWANCE

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 23, 2003 has been entered.

2. The following is an examiner's statement of reasons for allowance:

The claims are allowable over the prior art because the prior art does not teach an association between the IL-1A +4845 allele 2 or IL-1B -511 allele 2 and the occurrence of low birth weight babies. Accordingly, the prior art does not teach or suggest the claimed methods for determining whether a female subject is predisposed to having a low birth weight baby by detecting the presence of the IL-1A +4845 allele 2 or IL-1B -511 allele 2 as indicative of a predisposition to a low birth weight babies. Furthermore, Applicants arguments presented in the response of October 23, 2003 are persuasive regarding the non-obviousness of the claimed invention over the invention claimed in U.S. Patent No. 6,268,142. The claims in the '142 patent require the detection of an allelic pattern of two or more alleles as indicative of the occurrence of a disease associated with an IL-1 inflammatory haplotypes, wherein the alleles are selected from the group of 23 IL-1 alleles. On the other hand, the present claims require the detection of a single allele, either the IL-1A +4845 allele 2 or IL-1B -511 allele 2, as

indicative of a predisposition to having a low birth weight baby. While the '142 patent defines diseases associated with the IL-1 inflammatory haplotypes as including predisposition to a low birth weight baby, the claims of the '142 patent do not encompass or suggest that a single allele, namely the IL-1A +4845 allele 2 or IL-1B – 511 allele 2, could be detected as indicative of a predisposition to the occurrence of low birth weight babies.

3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers
November 5, 2003


CARLA J. MYERS
PRIMARY EXAMINER

CLAIMSPTO

C. DESSAU

11/13/03

1. (Previously presented) A method for determining whether a female subject is predisposed to having a low birth weight baby, said method comprising the steps of:
 - a) providing a nucleic acid sample from the subject; and
 - b) detecting an IL-1A (+4845) allele 2 or an IL-1B (-511) allele 2, wherein detection of said allele indicates that the subject is predisposed to having a low birth weight baby.
3. (Previously Presented) The method of claim 1, wherein said detecting is selected from the group consisting of allele specific oligonucleotide hybridization; size analysis; sequencing; hybridization; 5' nuclease digestion; single-stranded conformation polymorphism; allele specific hybridization; primer specific extension; and oligonucleotide ligation assay.
4. (Previously Presented) The method of claim 1, wherein prior to the detecting step, the nucleic acid sample is subject to an amplification step.
6. (Previously Presented) The method of claim 3, wherein said size analysis is preceded by a digestion with a restriction enzyme.

7. (Previously Presented) A method of claim 6, wherein said restriction enzyme is selected from the group consisting of: Nco I, Alu I and Msp I.

85. (Previously Presented) The method of claim 1, wherein said subject is pregnant.